## LAPT Rec'd PCT/FTO 27 FEB 2006

THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: The aye Biffu, et al.

Serial No. 10/556,805

Page 1 c

Filed: November 14, 2005

For: 3-AMINO-4-PHENYLBUTANOIC ACID DERIVATIVES AS DIPEPTIDYL PEPTIDASE INHIBITORS FOR THE

TREATMENT OR PREVENTION OF DIABETES

Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Art Unit: <u>To Be Assigned</u>

Examiner: <u>To Be Assigned</u>

## INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR 1.97

- Sir:
- 1. In compliance with 37 C.F.R. 1.97, submitted on the attached form herewith is a list of patents, publications or other information which are requested to be made of record in this application. This Information Disclosure Statement is not an admission that any patent, publication or other information referred to herein is "prior art" for this invention. In accordance with 37 C.F.R. 1.97(h), the filing of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. 1.56(b).
- 2. In accordance with 37 C.F.R. 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.
- 3. Applicants respectfully request that the Examiner initial the attached form after reviewing the pertinence of each reference.
- 4. Pursuant to 37 C.F.R. 1.98 (a)(2)(ii), copies of each cited U.S. patent and each U.S. patent application publication are not enclosed herewith.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450, on the date appearing below.

**MERCK & CO., INC.** 

By Derve Bron Date 3 12/2005

## INFORMATION DISCLOSURE STATEMENT

5. Pursuant to 37 C.F.R. 1.98(d), copies of references listed on the attached form that were submitted to or cited by the Office in a related application upon which the instant application relies for an earlier filling date under 35 U.S.C. 120 are not enclosed. Related application(s) in which references were submitted to or cited by the Office are as follows:

U. S. SERIAL NUMBER	FILING DATE	MERCK CASE
10/540,283	June 20, 2005	21304YP
10/537,476	June 3, 2005	21288YP
10/530,215	April 4, 2005	21239YP
10/542,694	July 19, 2005	21329YP

If th	this is inconvenient, additional copies will be submitted upon request.	
6	6. In accordance with 37 C.F.R. 1.97, (check one)	
	the attached information is filed within three months of the filing date of	of the captioned case.
$\checkmark$	the attached information is filed more than three months after the filing Office Action on the merits.	g date but prior to the mailing of a first
	the attached information is filed before the mailing of a first Office action examination under §1.114.	on after the filing of a request for continued
	the attached information is being filed more than three months after the Office Action on the merits, but before the mailing date of a Final Action otherwise closes prosecution in the application. The enclosed authority Account No. 13-2755 for the fee required under 37 C.F.R. 1.17(p).	on, Notice of Allowance, or an action that
	each item of information contained in this Information Disclosure State from a foreign patent office in a counterpart foreign application not mo Statement.	
	each item of information contained in the information disclosure stater a foreign patent office in a counterpart application and this communicated designated in §1.56(c) more than thirty days prior to the filing of the in	ation was not received by any individual
	no item of information contained in this Information Disclosure Statem foreign patent office in a counterpart foreign application, and, to the kr after making reasonable inquiry, was known to any individual designat months prior to the filing of this Statement.	nowledge of the person signing the certification
	Re	spectfully submitted,
		Sulgge & Owette
	By:	Philippe L. Durette
	<u>Att</u>	orney For Applicant(s)
	Re	g. No. <u>35,125</u>
		ERCK & CO., INC.
		tent Dept., RY60-30 D. Box 2000
		b. Box 2000 hway, N.J. 07065-0907
		32)594- <u>4568</u>
	Da	te: February 13, 2006

				Patent and Trademark Office; U.S DEPARTMENT OF COMMERCE
	Substitute for form 1449A/PTO			COMPLETE IF KNOWN
	INFORMATION DIS	CLOSURE	Application Number	10/556,805
	STATEMENT BY AF	DI ICANT	Filing Date	November 14, 2005
/b`	_ \	PLICANI	First Named Inventor	Tesfaye Biftu, et al.
FF	EB 27 2006 E	,	Group Art Unit	
\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\	(use as many sheets as n	ecessary)	Examiner Name	
	of	5	Attorney Docket Number	21404P

U.S. PATENT DOCUMENTS							
Examiner nitials*	Cite No.	U.S. Patent Document Number	Kind Code (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY		
	1	6,699,871 B2		Edmondson et al.	03/02/2004		
	2	6,011,155		Villhauer	01/04/2000		
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	7	4,386,090		Moinet et al	05/31/1983		
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r			Foreign Patent Document		Name of Bases and Associated	Date of Publication of			
Examiner Initials*	Cite No.	Office	Number	Kind Code (if known)	Name of Patentee or Applicant of Cited Document	Cited Document MM-DD-YYYY			
_	8	PCT	WO 03/082817 A2		MERCK & CO., INC.	10/09/2003			
	9	РСТ	WO 03/000180 A2		MERCK & CO., INC.	01/03/2003			
	10	PCT	WO 03/000181 A2		MERCK & CO., INC.	01/03/2003			
	11	РСТ	WO 03/000181 A3		MERCK & CO., INC.	01/03/2003			
	12	РСТ	WO 02/076450 A1		MERCK & CO., INC.	10/03/2002			
	13	PCT	WO 2004/007468 A1		MERCK & CO., INC.	01/22/2004			
	14	PCT	WO 2004/032836 A2		MERCK & CO., INC.	04/22/2004			
	15	PCT	WO 2004/050022 A2		MERCK & CO., INC.	06/17/2004			
	16	РСТ	WO 2004/058266 A1		MERCK & CO., INC.	07/15/2004			
	17	PCT	WO 2004/064778 A2		MERCK & CO., INC.	08/05/2004			

<sup>\*</sup>Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Examiner Signature Date Considered

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I	NFORMATION	DIS	CLOSURE	Application Number	10/556,805	
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3	TATEMENT BY	AP	PLICANI	First Named Inventor	Tesfaye Biftu, et al.	
				Group Art Unit		
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Sheet	2	of	5	Attorney Docket Number	21404P	

	U.S. PATENT DOCUMENTS							
Examiner Initials*	Cite No.	U.S. Patent Documer Number		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY			

	FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No.	Foreign Patent Document Office Number		Kind Code (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY			
	18	PCT	WO 2004/069162 A2		MERCK & CO., INC.	08/19/2004			
	19	PCT	WO 02/02560 A2		NOVO NORDISK A/S	01/10/2002			
	20	PCT	WO 01/96295 A2		NOVARTIS AG	12/20/2001			
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	22	PCT	WO 01/34594 A1		Guilford Pharmaceuticals, Inc.	05/17/2001			
	23	PCT	WO 00/34241		NOVARTIS AG	06/15/2000			
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	26	PCT	WO 97/40832		Hansknoll-Institut Fur Naturstoff-Forschung E.V.	11/06/1997			
	27	PCT	WO 03/000180 A3		MERCK & CO., INC.	01/03/2003			

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<sup>\*</sup>Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Su	Substitute for form 1449A/PTO		COMPLETE IF KNOWN				
I	NFORMATION 1	DIS	CLOSURE	Application Number	10/556,805		
c	TATEMENT BY	. A D	DI ICANT	Filing Date	November 14, 2005		
3	IAIEWENIBY	AP	PLICANI	First Named Inventor	Tesfaye Biftu, et al		
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U.S. PATENT DOCUMENTS							
Examiner Initials*	Cite No.	U.S. Patent Document Number		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY		
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Examiner Initials*	Cite No.	Foreign Patent Document Office Number		Kind Code (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
	28	PCT	WO 02/02560	A3	NOVO NORDISK	01/10/2002
	29	PCT	WO 01/42262		AKZO NOBEL N.V.	06/14/2001
	30	PCT	WO 2004/043940		MERCK & CO., INC.	05/27/2004
	31	PCT	WO 2004/007468		MERCK & CO., INC.	01/22/2004
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	37	PCT	WO 2005/002530	A2	SMITHKLINE BEECHAM CORP.	01/09/2003

Examiner	Date
Signature	Considered

<sup>\*</sup>Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

					TECH ED THEMEN ONCE, O.S DETARTMENT OF COMMERCE	
Substitute for form 1449A/PTO		COMPLETE IF KNOWN				
	INFORMATION	DIS	CLOSURE	Application Number	10/556,805	
STATEMENT BY APPLICANT				Filing Date	November 14, 2005	
	SIAIEMENIB	r Ar	PLICANI	First Named Inventor	Tesfaye Biftu, et al.	
				Group Art Unit		
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Shee	t 4	of	5	Attorney Docket Number	21404P	

		U.S. PA	TENT DOCUMENTS	
Cite No.	U.S. Patent Document Number	Kind Code (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
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			FOREIC	N PATENT	T DOCUMENTS	
Examiner Cite Initials* No.		Office	Foreign Patent Document Number	Kind Code (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
	38	PCT	WO 2005/056003	A1	GRAFFINITY PHARMACEUTICALS AG	06/23/2005
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	40	PCT	WO 2005/108382	A1	MERCK & CO., INC.	11/17/2005
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	42	PCT	WO 2005/123685	A1	ASTRAZENECA AB	12/29/2005

Examiner Signature Date Considered

<sup>\*</sup>Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT  (use as many sheets as necessary)		COMPLETE IF KNOWN				
	N DIS	CLOSURE	Application Number	10/556,805		
TATEMENT D	VAD	DI ICANT	Filing Date	November 14, 2005		
STATEMENT BY APPLICANT		First Named Inventor	Tesfaye Biftu, et al.			
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	NFORMATION TATEMENT B	NFORMATION DISC TATEMENT BY AP (use as many sheets as no	NFORMATION DISCLOSURE  TATEMENT BY APPLICANT  (use as many sheets as necessary)	TATEMENT BY APPLICANT  (use as many sheets as necessary)  Application Number  Filing Date  First Named Inventor  Group Art Unit  Examiner Name		

		NON PATENT LITERATURE DOCUMENTS
Examiner Initials*	Cite No.	Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.
	43	J. J. Holst, "Treatment of Type 2 Diabetes Mellitus with Agonists of the GLP-1 Receptor or DPP-IV Inhibitors", Expert Opin. Emerg. Drugs, Vol. 9(1) pp. 155-166(2004).
	44	C. F. Deacon, et al., "Inhibitors of dipeptidyl peptidase IV: A Novel Approach for the Prevention and Treatment of Type 2 Diabetes?", Expert Opin. Investig. Drugs, Vol. 13(9) pp. 1091-1102( 2004).
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	49	L. B. Knudsen, "Glucagon-like peptide-1: The Basis of a New Class of Treatment for Type 2 Diabetes", J. Med. Chem, Vol. 47, pp. 4128-4134 (2004).
	50	A. E. Weber, "Dipeptidyl Peptidase IV Inhibitors for the Treatment of Diabetes", J. Med. Chem, Vol. 47, pp. 4135-4141 (2004).
	51	J. J. Holst and C. F. Deacon, "Glucagon-like peptide 1 and inhibitors of dipeptidyl peptidase IV in the treatment of type 2 diabetes mellitus", Curr. Opin Pharmacology, Vol. 4, pp. 589-596 (2004).
	52	C. F. Deacon, "Perspectives in Diabetes - Therapeutic Strategies Based on Glucagon-Like Peptide 1", Diabetes, Vol. 53, pp. 2181-2189 (2004).
	53	K. Augustyns, et al., "Inhibitors of proline-specific dipeptidyl peptidase: DPP IV inhibitors as a novel approach for the treatment of Type 2 diabetes", Expert Opin. Ther. Patents, Vol. 15(10), pp. 1387-1407 (2005).
	54	Hans-Ulrich Demuth, et al., " Type 2 diabetes - Therapy with dipetidyl peptidase IV inhibitors", Biochimica et Biophysica Acta, Vol. 1751, pp., 33-44 (2005).
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Examiner	Date
Signature	Considered

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